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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,843	07/28/2003	Leonard S. Schultz	6971.02	5820

7590 05/16/2006

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EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/628,843	SCHULTZ, LEONARD S.	
	Examiner	Art Unit	
	Diane Yabut	3734	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-37 is/are pending in the application.
- 4a) Of the above claim(s) 21-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/25/05; 1/10/05</u>  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121.

This application contains claims directed to the following patentably distinct species of the claimed invention. The species are as follows:

<u>Species</u>	<u>Figure</u>
1	3
2	4

There are no generic claims.

2. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

3. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

4. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

6. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

7. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

8. During a telephone conversation with David E. Bruhn on Tuesday, May 9, 2006 a provisional election was made without traverse to prosecute the invention of Species 2 directed towards Figure 4 and Claims 29-37. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21-28, which read on Species 1, are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Information Disclosure Statement***

9. The information disclosure statement (IDS) submitted on 10 January 2005 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Also, the IDS submitted on 25 April 2005 is acknowledged. Accordingly, the information disclosure statement is being considered by the examiner. However, the non-patent literature disclosed could not be considered by the examiner of 10 January 2005, and applicant should resubmit the documents listed.

***Specification***

10. The abstract of the disclosure is objected to because it does not include or mention the plurality of openings and biological bonding agent elements, as well as the different materials it comprises (biphasic, biosorbable, and shape memory). Applicant should mention the elements above. Correction is required. See MPEP § 608.01(b).

11. The disclosure is objected to because of the following informalities: On page 1, lines 6-7, it reads "In one exemplary use, The" and should be changed to --In one exemplary use, the--. On page 5, line 8, it reads "an useful" and should instead read --a useful--. On page 6, line 4 it reads "shape like tooth" and should be changed to --tooth-like shape--. On page 6, line 17 it reads "as concerns" and should be changed to --concerning--. On page 14, line 4, it reads "detach and withdraw" and should instead read --detaches and withdraws--. Appropriate correction is required.

12. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 2, line 19. Applicant is required to

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delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 29 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (U.S. Patent No. **5,292,332**) in view of Clark et al. (U.S. Patent No. **5,259,835**).

Claim 29: Lee discloses a plug **22** and a delivery instrument **34** detachably coupled to the plug **22** for moving to a selected location (Figure 1 and col. 4, lines 49-51 and col. 5, lines 42-46) and a biological bonding agent **57**. Lee discloses the claimed device except for the plug **22** having a plurality of openings through which the biological bonding agent is moved.

Clark et al. teaches a wound closure device **36** having a plurality of openings into which a biological bonding agent permeates (col. 3, lines 47-50). Clark et al. teaches that the porous structure of the device serves as a matrix for the adhesive (col. 3, lines 51-53). It would have been obvious to one of ordinary skill in the art to add a plurality of openings, as taught by Clark et al., to the device of Lee, in order to provide a suitable bonding material, or matrix, for the biological bonding agent.

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Claim 34: Lee discloses a device with a plugging means **22** adapted for occluding a body lumen and a delivery means **34** that is detachably coupled to the plugging means (see explanation for Claim 29 above). Lee discloses inserting the device adapted for occluding a body lumen with the plugging means entering the puncture orifice **24** ("lumen") first and advancing the device to a target site (Figure 4 and col. 5, lines 24-31). Lee discloses detaching the delivery means **34** from the plugging means **22** and withdrawing the delivery means **34** from the puncture orifice **24**, leaving the plugging means **22** inside the puncture orifice **24** (Figure 6, col. 5, lines 42-26).

Lee discloses the claimed device except for the plugging means having a plurality of openings, injecting a biphasic material into the delivery means and conveying the biphasic material to the plugging means, and moving the biphasic material through the openings of the plugging means to fix the plugging means relative to the interior wall of the body lumen.

Clark et al. teaches the plurality of openings through which the biological bonding agent is moved (see explanation for Claim 29 above). Clark et al. teaches the injection of biphasic material **57** through a delivery means **34** and conveying it into a bonding pad **36** ("plugging means") and wherein the biphasic material **57** moves through the openings of the bonding pad **36**, and is adapted to be fixed to the interior of a body lumen (col. 4, lines 3-21). It would have been obvious to provide a plurality of openings, and therefore the injecting and moving of the biphasic material steps, as taught by Clark et al., to the device of Lee, in order to provide a suitable bonding material, or matrix for the biological bonding agent (see explanation for Claim 29 above).

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15. Claims 30-33 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lee** (U.S. Patent No. **5,292,332**) and **Clark et al.** (U.S. Patent No. **5,259,835**), as applied to Claims 29 and 34 above, and further in view of **Wallace et al.** (U.S. Patent No. 6,585,754).

Claims 30-33 and 35-37: Lee and Clark et al. disclose the claimed device except for the bonding agent comprising a biphasic material, a biosorbable material, a shape memory material, and the biphasic material being biosorbable and a shape memory material.

Wallace et al. teaches the use of biphasic material and biosorbable material (col. 4, lines 48-57) and shape memory material (col. 4, lines 41-45), wherein the the biosorbable and shape memory materials are biphasic, in the art of vaso-occlusive members. Wallace et al. teaches that the use of these materials encourages greater tissue ingrowth, and therefore more stable occlusions (col. 4, lines 15-17). It would have been obvious to one of ordinary skill in the art to have the bonding agent comprise biphasic, biosorbable, and shape memory material, as taught by Wallace et al., to Lee and Clark et al., in order to provide greater tissue ingrowth and therefore a more stable occlusion in the body lumen.

### ***Conclusion***

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **Ginn et al.** (U.S. Patent No. **6,846,319**) discloses a biosorbable plug detachably coupled to an elongate shaft.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**MICHAEL J. HAYES**  
**PRIMARY EXAMINER**